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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/709,774 | 11/08/2000 | Alessandro Sette | 18623006240 | 3936 |

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EXAMINER

VANDERVEGT, FRANCOIS P

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/709,774

Applicant(s)

SETTE ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 08/305,871, which is a continuation-in-part of U.S. Application Serial Number 08/121,101, and is a continuation-in-part of U.S. Application Serial Number 08/788,822, which claims the benefit of the filing date of provisional applications 60/082,250, 60/101,580 and 60/010,510.

Claims 1-17 have been canceled previously.

Claims 27-65 have been canceled presently.

Claims 18-26 are currently pending and are the subject of examination in the present Office Action.

Priority

1. Applicant is not entitled to priority to 08/305,871 due to lack of support for the pending claims for the reasons of record.

In view of Applicant's amendment filed December 10, 2003 the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-26 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was previously stated: "Base claim 18, first entered as a new claim in the preliminary amendment filed November 8, 2000, is drawn to a polynucleotide encoding a fusion protein which comprises a pan-DR binding peptide of the formula $R_1-R_2-R_3-R_4-R_5$, wherein " R_1 is an amino acid followed by an alanine or lysine" and " R_5 consists of 2 to 4 amino acids followed by an amino acid wherein each of the 2 to 4 amino acids is independently selected from the group consisting of alanine,

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serine and valine.” The recitation of “an amino acid” for both R_1 and R_5 is not supported by the specification or claims as originally filed and constitutes new matter.

In the remarks accompanying the preliminary amendment filed November 8, 2000 Applicant positions that “[a]ll support” for the new claims is “provided with reference to the ‘142 patent” [a.k.a., U.S. Patent No. 5,736,142]. It is acknowledged that the ‘142 patent was issued from the parent application 08/305,871 and that the specification of the instant application is identical to the specification of the ‘871 application as originally filed on September 14, 1994. However, it is improper to rely upon the citation of passages in the ‘142 patent for support of amendments to the instant specification and claims. Support should be pointed out within the instant specification and/or claims as originally filed.

In the present case, the specification at page 4, lines 16-36, discloses “ R_1 is a D-amino acid followed by alanine or lysine” and “ R_5 consists of 2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine.” The specification does not provide other, alternative, definitions for R_1 and R_5 . Applicant contends in the remarks accompanying the preliminary amendment filed November 8, 2000 that because “the pan DR peptides of the invention can be synthesized via recombinant DNA techniques, it is clear that pan DR peptides need not include D-amino acids.” However, R_1 and R_5 have been defined in the specification in an absolute, not alternative, manner. Applicant is reminded that obviousness is not the standard for the addition new limitations to the disclosure as filed. Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, a limitation for either/each of R_1 or/and R_5 to include “an amino acid” which is not “a D-amino acid” may be obvious over recombinant technology but is not supported by the specification or claims as originally filed. Applicant’s assertion in the remarks accompanying the preliminary amendment filed November 8, 2000 that “claim 34 of the ‘142 patent is directed to pan DR peptides with the exact same amino acid sequences recited in claim 78 [sic; claim 18 per Rule 126] of the present application” is acknowledged. However, it is noted that claim 34 of the ‘142 patent was added during prosecution and was not originally presented in the ‘871 application from which it issued.”

Applicant’s arguments filed December 10, 2003 have been fully considered but are not persuasive. Applicant asserts that the amino acid residues located at positions R_1 and R_5 are non-critical amino acids because they are not within a core binding region or at critical contact sites. Applicant asserts that because of this, the specification teaches at page 16, lines 24-31 of the instant specification that the amino acid residues at R_1 and R_5 are not limited to being D amino acid residues. Applicant further asserts that there is no requirement for a pan DR-binding peptide to contain any D-amino acid. The Examiner respectfully disagrees with Applicant’s position. The claims are drawn to and recite pan-DR peptides of the formula $R_1-R_2-R_3-R_4-R_5$. in order to recite a peptide of the formula “ $R_1-R_2-R_3-R_4-R_5$ ” in the claim, the formula “ $R_1-R_2-R_3-R_4-R_5$ ” MUST be defined in the specification. There is only one place in the specification that the formula “ $R_1-R_2-R_3-R_4-R_5$ ” is defined, and that place is at page 4, lines 16-36 of the specification as filed. In said definition of the formula “ $R_1-R_2-R_3-R_4-R_5$ ” at page 4, lines 16-36, “ R_1 ” is defined as “a D-amino acid followed by alanine or lysine” and “ R_5 ” is defined as “2 to 4 amino acids followed by a D-amino acid where each of the 2 or 4 amino acids is independently selected from the group consisting of alanine, serine and valine.” This is not, as asserted by Applicant, a “preferred

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embodiment," rather it is a specific definition of what the claims mean by reciting the formula " R_1 - R_2 - R_3 - R_4 - R_5 ." Accordingly, despite Applicant's assertion that there "is never any requirement for a pan DR-binding peptide to contain any D-amino acid," there is a requirement in the specification for a peptide of the formula " R_1 - R_2 - R_3 - R_4 - R_5 " to contain D amino acids at both " R_1 " and " R_5 ."

Conclusion

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*
Patent Examiner
April 1, 2004

Pat J. Nolan
PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

4/5/04